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10/573,771	09/24/2008	Yasushi Kanno	403664/SKY	3996
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LEYDIG VOIT & MAYER, LTD			EXAMINER	
700 THIRTEENTH ST. NW			HICKS, VICTORIA J	
SUITE 300				
WASHINGTON, DC 20005-3960			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/573,771	Applicant(s) KANNO, YASUSHI
	Examiner VICTORIA HICKS	Art Unit 3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 September 2010.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 3-19 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 3-19 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 28 March 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/IDS/06)
 Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

This action is in response to the amendment filed on 9/23/10. Currently, claims 3-19 are pending in the application. Claims 1 and 2 were cancelled by Applicant and new claims 3-19 were added by Applicant.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 7 and 15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 7 and 15 recite that "the rotor is a material selected from the group consisting of rubber, metal, plastics, ceramics, and glass." No support has been provided in the specification for this claim limitation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 3-8, 11-15, 16 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugawa (US 2004/0089309) in view of Griffiths (US 2002/0139373).

In regards to claims 3 and 13, Tsugawa teaches in Figures 1, 2 and 14, the abstract, [0080] and [0086] a condom (1) having a tubular region with an opening and having an inside diameter; and a ring (82, 83) on which the condom (1) is rolled, with the opening of the tubular region of the condom (1) expanded, wherein the ring (82, 83) comprises a rigid ring (82) having an outside diameter larger than the inside diameter of the tubular region of the condom (1) and sufficiently rigid to withstand compression by the condom (1), a rotor (83) that is a sheath covering (is located on) the rigid ring (82), the rotor (83) being rotatable with respect to the rigid ring (82), the ring (82, 83) being removable from the condom (1) after unrolling of the condom (1) from the ring (82, 83) by rotation of the rotor (83). Tsugawa does not teach a lubricant located between the rigid ring and the rotor. However, Griffiths teaches in [0027] an analogous device with a lubricant located between the rigid ring (installation ring) and the rotor (rolled up condom). It would have been obvious to modify the ring taught by Tsugawa with the lubricant taught by Griffiths because this element is known to make the condom simpler to use, as Griffiths teaches in [0014].

In regards to claim 4, Tsugawa and Griffiths teach the apparatus of claim 3. Tsugawa teaches in Figures 1, 2 and 14 and [0080] that the tubular region of the condom (1) includes at least two tubular regions having respective different inside

diameters, and the tubular region of the condom (1) able to be rolled onto and off of the ring (82, 83) by rotation of the rotor (83) with respect to the rigid ring (82).

In regards to claim 5, Tsugawa and Griffiths teach the apparatus of claim 3.

Tsugawa teaches in [0080] and Figures 1 and 2 that the ring (82, 83) is removably attached at the opening of the tubular region of the condom (1).

In regards to claims 6, 7, 11, 14 and 15, Tsugawa and Griffiths teach the apparatus of claims 3 and 13. Tsugawa and Griffiths do not teach that the rigid ring is a material selected from the group consisting of metals, plastics, hard rubber, ceramics, and glass, that the rotor is a material selected from the group consisting of rubber, metal, plastics, ceramics, and glass or that the rotor and the condom are made of the same material. However, it would have been obvious to one having ordinary skill in the art at the time of invention to provide the rigid ring being a material selected from the group consisting of metals, plastics, hard rubber, ceramics, and glass, the rotor being a material selected from the group consisting of rubber, metal, plastics, ceramics, and glass and that the rotor and the condom being made of the same material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

In re Leshin, 126 USPQ 416.

In regards to claims 8 and 16, Tsugawa and Griffiths teach the apparatus of claims 3 and 13. Tsugawa teaches in Figure 14 and [0086] that the rotor (83) is bead-shaped.

In regards to claims 12 and 19, Tsugawa and Griffiths teach the apparatus of claims 3 and 13. Tsugawa and Griffiths disclose the claimed except for the lubricant including fluorine-containing oil. It would have been obvious to one having ordinary skill in the art at the time of invention to provide the lubricant including a fluorine-containing oil, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 126 USPQ 416.

3. Claims 9 and 17 rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugawa (US 2004/0089309), in view of Griffiths (US 2002/0139373) and further in view of Taller et al. (US 4,817,593).

In regards to claims 9 and 17, Tsugawa and Griffiths teach the apparatus of claims 3 and 13. Tsugawa and Griffiths do not teach that the lubricant is a dry lubricant film. However, Taller et al. teaches in column 9, lines 18-22 an analogous device in which the lubricant is a dry lubricant. It would have been obvious to one having ordinary skill in the art at the time of invention to modify the lubricant taught by Tsugawa as modified by Griffiths with the dry lubricant taught by Taller et al. because this element is known to be a commonly used lubricant in the art, as Taller et al. teaches in column 9, lines 18-22.

4. Claims 10 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsugawa (US 2004/0089309), in view of Griffiths (US 2002/0139373) and further in view of Wang et al. (US 2004/0118408).

In regards to claims 10 and 18, Tsugawa and Griffiths teach the apparatus of claims 3 and 13. Tsugawa and Griffiths do not teach that the lubricant includes a bead-shaped member. However, Wang et al. teaches in the abstract an analogous device in which the lubricant includes a bead-shaped member (micro-bead). It would have been obvious to one having ordinary skill in the art at the time of invention to modify the lubricant taught by Tsugawa as modified by Griffiths with the bead-shaped member taught by Wang et al. because this element is known to decrease or prevent the risk of pathogenic microbial and viral infection and maintain the vaginal environment in good condition, as Wang et al. teaches in the abstract.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. In response to Applicant's argument that the ring structure of the present claims is not described or suggested by Tsugawa, the examiner respectfully disagrees. Tsugawa teaches in Figures 1, 2 and 14, the abstract, [0080] and [0086] a condom (1) having a tubular region with an opening and having an inside diameter; and a ring (82, 83) on which the condom (1) is rolled, with the opening of the tubular region of the condom (1) expanded, wherein the ring (82, 83) comprises a rigid ring (82) having an outside diameter larger than the inside diameter of the tubular

region of the condom (1) and sufficiently rigid to withstand compression by the condom (1), a rotor (83) that is a sheath covering (is located on) the rigid ring (82), the rotor (83) being rotatable with respect to the rigid ring (82), the ring (82, 83) being removable from the condom (1) after unrolling of the condom (1) from the ring (82, 83) by rotation of the rotor (83). In response to Applicant's argument that the auxiliary device of Tsugawa does not expand the tubular region of the condom as claimed, the examiner notes that Tsugawa clearly teaches in Figure 1 that the auxiliary device expands the tubular region of the condom.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA HICKS whose telephone number is (571)270-7033. The examiner can normally be reached on Monday through Thursday, 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/V. H./
Examiner, Art Unit 3772
12/2/10

/Patricia Bianco/
Supervisory Patent Examiner, Art Unit 3772